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# Common Sense Initiative

Mike DeWine, Governor Jim Tressel, Lt. Governor Joseph Baker, Director

### **MEMORANDUM**

**TO:** Summer Reyburn, Ohio Board of Pharmacy

**FROM:** Michael Bender, Business Advocate

**DATE:** August 29, 2025

RE: CSI Review – Administration of Drugs by Injection and Dispensing Drugs to an

Alternate Location (OAC 4729:1-3-03, 4729:5-3-24, and 4729:5-5-14)

Pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Board as provided for in ORC 107.54.

### **Analysis**

This rule package consists of one new rule, one amended rule, and one rescinded rule proposed by the Ohio Board of Pharmacy (Board). This rule package was submitted to the CSI Office on June 5, 2025, and the public comment period was held open through June 30, 2025. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on June 5, 2025.

Ohio Administrative Code (OAC) 4729:1-3-03 authorizes licensed pharmacists to administer drugs by injection under certain conditions. The rule is amended to allow advanced practice registered nurses (APRNs) to authorize protocols for drug administration, recognize certification to perform basic life-support (BLS) procedures from the American Safety and Health Institute (ASHI), add several new drugs that may be administered via prescription and pursuant to protocol, and prohibit intravenous drug administration. OAC 4729:5-3-24 is a new rule that establishes standards for pharmacies to dispense dangerous drugs to locations other than a patient's or caregiver's address

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such as a clinic, hospital, or prescriber office. The rule replaces OAC 4729:5-5-14, which concerns prescription pick-up stations and is proposed for rescission.

During early stakeholder outreach, the Board distributed the rules to interested parties for public comment and posted the package on its proposed rules webpage. Stakeholders submitted several requests to allow various drugs to be administered by pharmacists. The Board revised the rules to allow human immunodeficiency virus prevention medications, antibiotics, denosumab, romosozumab, methotrexate, heparin, low molecular weight heparin, and factor Xa inhibitors to be administered by pharmacists via injection. However, the Board determined that other requested drugs were not appropriate for pharmacist administration. Comments were also submitted asking for additional allowances to return dispensed drugs to stock. The Board incorporated this change into the rules. During the CSI public comment period, the Board received comments from ProMedica Health System (ProMedica), the Ohio Pharmacists Association (OPA), the Ohio Association of Physician Assistants (OAPA), and the State Medical Board of Ohio (Medical Board).

The OPA supported the changes to the rules but recommended delineating training requirements for dangerous drugs – live of home study, sterile technique, proper disposal, needlesticks – live or home study, and injection technique – live and supervised. The Board agreed to align the required training with the OPA's recommendations. ProMedica suggested adding training and competency for hazardous drug handling and storage to prevent accidental harmful pharmacist or non-prescribed patient exposure. The Board added a requirement to protocol instructions to include any special handling instructions, precautions, or use of personal protective equipment if available. The OAPA requested that the Board restore language recognizing physician assistants who have entered in supervision agreements with physicians as authorized prescribes. The Board explained that this requires a legislative change, as physician assistants are not specified in statute along with other midlevel prescribers. The Medical Board believed that the injection of methotrexate should occur in a physician's office rather than a pharmacy. To address the Medical Board's concerns, the Board clarified that methotrexate administered in pharmacies may only be done for non-emergent conditions. The Medical Board expressed additional concerns about allowing the injection of medroxyprogesterone acetate and hydroxyprogesterone caproate in pharmacies, but the Board noted that these drugs are specifically authorized in statute. At the request of the Medical Board, the Board also revised the rules to address privacy concerns, clarify that injection includes subcutaneous or intramuscular methods, and change references of "opioid antagonist" to "addiction treatment drug."

The business community impacted by the rules includes pharmacists and terminal distributors of dangerous drugs. The adverse impacts created by the rules include the standards for administering drugs via injection and dispensing dangerous drugs to alternate locations. Pharmacists are required to complete training in drug administration. The OPA offers training for pharmacists that costs \$295 for members and \$425 for non-members. A pharmacist or terminal distributor of dangerous drugs

may also face administrative licensure discipline for a violation of the rules. Such discipline may include reprimand, continuing education, a monetary fine, and/or suspension or revocation of a license. The Board notes that the adjustments made in this package add more allowances to return dispensed drugs to stock if a pharmacy that dispenses a drug is under common ownership and control as the receiving terminal distributor of dangerous drugs. Furthermore, the changes to the rules allow APRNs to authorize protocols for drug administration, recognize certification to perform BLS procedures from the ASHI, and add several new drugs that may be administered via prescription and pursuant to protocol. The Board states that the adverse impacts to business are justified to reflect changes in Ohio law, protect and promote public safety, and protect the health and safety of patients by ensuring the safe administration of dangerous drugs.

# Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

## **Conclusion**

The CSI Office concludes that the Board should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.